Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BIONIME CORPORATION
C/O FENG-YU LEE
IVDD REGULATORY CONSULTANT
29222 RANCHO VIEJO ROAD, SUITE 218
SAN JUAN CAPISTRANO CA 92675

August 22, 2014

Re: K140210
Trade/Device Name: Bionime Rightest™ Blood Glucose Monitoring System GM720, Bionime Rightest™ Professional Blood Glucose Monitoring System GM720
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: August 15, 2014
Received: August 18, 2014

Dear Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140210

Device Name
Rightest Professional Blood Glucose Monitoring System GM720

Indications for Use *(Describe)*
The Rightest Professional Blood Glucose Monitoring System GM720 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm and in venous and arterial whole blood. The Rightest Professional Blood Glucose Monitoring System GM720 is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The Rightest Professional Blood Glucose Monitoring System GM720 should not be used for the diagnosis of, or screening for diabetes, nor for testing neonate blood samples. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Professional Blood Glucose Test Strips GS720 are for use with the Rightest Professional Blood Glucose Meter GM720 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm and in venous and arterial whole blood samples.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140210

Device Name
Rightest Blood Glucose Monitoring System GM720

Indications for Use *(Describe)*
The Rightest Blood Glucose Monitoring System GM720 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM720 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM720 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM720 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS720 are for use with the Rightest Blood Glucose Meter GM720 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: k140210

1. Submitter's Identification:

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NO 100, Sec. 2, Daqing St., South Dist., 40242 Taichung City, Taiwan
Contact Person: Mr. Roy Huang
Phone Number: 886-4-23692388
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Date Summary Prepared: August 20, 2014

2. Contact Persons:

Primary Contact:
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3. Name of the Device:
Rightest Blood Glucose Monitoring System GM720
Rightest Professional Blood Glucose Monitoring System GM720

4. Common or Usual Name: Glucose test system

Product Code	Classification	Regulation Section	Panel
NBW; System, Test, Blood Glucose, Over-the-Counter	Class II	21 CFR 862.1345	Clinical Chemistry 75
LFR; Glucose Dehydrogenase, Glucose	Class II	21 CFR 862.1345	Clinical Chemistry 75

4. Device Description:

The Rightest Blood Glucose Monitoring System GM720 consists of the following devices: Rightest Blood Glucose Meter GM720, Rightest Blood Glucose Test Strip GS720, Rightest Control Solution GC700, lancing device and sterile lancets. The Rightest Blood Glucose Meter GM720, Rightest Blood Glucose Test Strips GS720, and Lancing Device are manufactured by BIONIME Corporation.

The Rightest Professional Blood Glucose Monitoring System GM720 consists of the following devices: Rightest Professional Blood Glucose Meter GM720, Rightest Professional Blood Glucose Test Strip GS720, and Rightest Control Solution GC700. This system should only be used with auto-disabling, single-use lancing devices and sterile lancets. The Rightest Professional Blood Glucose Meter GM720 and Rightest Professional Blood Glucose Test Strips GS720 are manufactured by BIONIME Corporation.

5. Intended Use:

Device Name: Rightest Blood Glucose Monitoring System GM720
The Rightest Blood Glucose Monitoring System GM720 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM720 is intended to be used by a single person and should not be shared.
The Rightest Blood Glucose Monitoring System GM720 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM720 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).
The Rightest Blood Glucose Test Strips GS720 are for use with the Rightest Blood Glucose Meter GM720 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Device Name: Rightest Professional Blood Glucose Monitoring System GM720
The Rightest Professional Blood Glucose Monitoring System GM720 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm and in venous and arterial whole blood. The Rightest Professional Blood Glucose Monitoring System GM720 is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The Rightest Professional Blood Glucose Monitoring System GM720 should not be used for the diagnosis of, or screening for diabetes, nor for testing neonate cord blood samples. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).
The Rightest Professional Blood Glucose Test Strips GS720 are for use with the Rightest Professional Blood Glucose Meter GM720 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm and in venous and arterial whole blood samples.

6. Predicate Devices Information:

The Rightest Blood Glucose Monitoring System GM720 and Rightest Professional Blood Glucose Monitoring System GM720 are substantially equivalent to the following device:

Name:	ACCU-CHEK Performa Blood Glucose Monitoring System
Device Company:	Roche Diagnostics Corporation
510(K) Number:	K070585

7. Comparisons to Predicate Devices:

Specification Comparison

	Candidate Device	Predicate Device
	Rightest Professional GM720	ACCU-CHEK Performa BGMS (K070585)
Intended Use	It is intended to be used for quantitative measurement of glucose in fresh whole blood as an aid to monitor the effectiveness of diabetes control.	Same
Measuring Range	20-600 mg/dL	10-600 mg/dL
Testing Samples	Fresh capillary whole blood from the fingertips, palm, forearm. Venous Whole Blood Arterial Blood	Fresh capillary whole blood from the fingertips, palm, forearm, upper arm, thigh and calf. Venous Whole Blood Neonatal Blood Arterial Blood
Measurement Technology	Dehydrogenase Electrochemical Sensor	Same
Strip Reagent	FAD-glucose Dehydrogenase: 12.1% Potassium ferricyanide: 48.5% Non-reactive ingredients: 39.4%	Mediator: 6.72% Quinprotein glucose dehydrogenase: 15.27% Pyrroloquinoline quinone: 0.14% Buffer: 34.66% Stabilizer: 0.54% Non-reactive ingredients: 42.66%
Test Time	5 seconds	Same
Coding	Auto-coding	Code Key
Operating Temperature Range	43 ~111°F (6 ~ 44°C)	40~113°F (8 ~ 44°C)
Operating Relative Humidity Range	10-90%	Same
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30°C), 10-90% relative humidity	59~86°F (2 ~ 30°C)
Minimum Sample Volume	0.75 µL	0.6 µL
Hematocrit Range	20-65%	10-70%
Memory Capacity	1000 blood glucose test results with date and time	500 blood glucose test results with date and time
Meter Dimensions	71.5 × 39.5 × 14.0 mm (LWH)	93 x 52 x 22 mm (LWH)
Meter weight	50.0 ± 5 g with batteries	62 g with battery

8. Technology Characteristics:

Biomine's Rightest™ GM720 system is an electronic device that utilizes the electrical characteristic technology for measuring the glucose level in human blood. A relatively small drop of blood is placed on a disposable test strip coated with FAD-glucose Dehydrogenase (FAD-GDH). Within five seconds, the level of blood glucose will be shown on the digital display screen.

Rightest™ Blood Glucose Monitoring System GM720, with an auto-coding feature, requires only minimum of 0.75 microliter of blood for the testing, therefore it reduces the time and effort required for testing and improves the compliance of diabetic people to their testing regimens.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of the Rightest Blood Glucose Monitoring System GM720. The evaluation included precision, linearity, interference, sample volume and hematocrit.

10. Discussion of Clinical Tests Performed:

System Accuracy Study:

The accuracy study of the Rightest Blood Glucose Monitoring System GM720 was performed by comparing whole blood (plasma equivalent) glucose values on the Rightest Blood Glucose meter GM720 with plasma glucose values on a lab instrument.
A total of 121 patients were recruited. The study result demonstrates that the accuracy of Rightest Blood Glucose Monitoring System GM720 met the acceptance criteria.

User Performance Study:

A User Performance Evaluation Study was performed to demonstrate that lay users could obtain accurate results using the subject device. The study was performed using capillary whole blood from fingertip, palm and forearm sample sites by evaluating total of 165 laypersons in multiple sites. The study result shows substantial equivalence to predicate device used in finger, palm and forearm position.

11. Conclusions:

Results of performance evaluation of the Rightest Blood Glucose Monitoring System GM720 demonstrate that the Rightest BGMS and Rightest Professional BGMS GM720 are substantial equivalence to the predicate device, ACCU-CHEK Performa Blood Glucose Monitoring System.